



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/809,240

03/25/2004

Shoji Miyazaki

55220/845

6687

1912

7590

10/17/2008

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

10/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,240	Applicant(s) MIYAZAKI ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/25/2004 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 09/889,243.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/15/2008</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS of 3/25/2004 and IDS of 4/16/2007.</u> |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Double Patenting Rejections based on US 6,875,327 B1

2. Claims 45-47 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,875,327 B1 ("Miyazaki"). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 14 of Miyazaki meets all of the limitations of claims 45-47 and 49 of the instant application. For the rejection of claim 46 the fourth type of slits in claim 14 of Miyazaki can be construed as the second type of slits in claim 46 of the instant application. For the rejection of claim 47 the fourth type of slits in claim 14 of Miyazaki can be construed as the third type of slits in claim 47 of the instant application.

3. Claim 48 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 13 and 14 of Miyazaki. Claim 47, from which claim 48 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 meets the additional limitations of claim 48.

Art Unit: 1795

4. Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 3, 13, and 14 of Miyazaki. Claim 45, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 3 meets the additional limitations of claim 51.

5. Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 4 and 14 of Miyazaki. Claim 45, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 meets the additional limitations of claim 52.

6. Claim 53 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 5 and 14 of Miyazaki. Claim 49, from which claim 53 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 meets the additional limitations of claim 53.

Art Unit: 1795

7. Claim 54 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 6 and 14 of Miyazaki. Claim 53, from which claim 54 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 meets the additional limitations of claim 53.

8. Claim 55 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 7 and 14 of Miyazaki. Claim 45, from which claim 55 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 meets the additional limitations of claim 55.

9. Claim 56 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 8 and 14 of Miyazaki. Claim 55, from which claim 56 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 meets the additional limitations of claim 56.

10. Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 9 and 14 of Miyazaki. Claim 45, from which claim 57 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 meets the additional limitations of claim 56.

11. Claim 58 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 10 and 14 of Miyazaki. Claim 45, from which claim 58 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 10 meets the additional limitations of claim 58.

12. Claim 59 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 11 and 14 of Miyazaki. Claim 58, from which claim 59 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 meets the additional limitations of claim 58.

13. Claim 60 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 15, 10, 12, and 14 of Miyazaki. Claim 45, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10, 12, and 14 together meets the additional limitations of claim 60. Note that second type of slits in claim 10 of Miyazaki can be construed as the claimed fourth type of slits.

14. Claim 61 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 16, 15, 10, 12, and 14 of Miyazaki. Claim 60, from which claim 61 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 meets the additional limitations of claim 61.

15. Claims 62 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 18 and 14 of Miyazaki. Claim 45, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 18 meets the additional limitations of claim 62.

16. Claims 63 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 19 and 14 of Miyazaki. Claim 45, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 meets the additional limitations of claim 63.

17. Claims 64 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 20 and 14 of Miyazaki. Claim 45, from which claim 64 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 meets the additional limitations of claim 64.

18. Claims 65 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 21 and 14 of Miyazaki. Claim 45, from which claim 65 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 21 meets the additional limitations of claim 62.

Double Patenting Rejections based on US Patent Application No. 10/809,217

19. Claims 45-47 and 58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 59 of copending Application No. 10/809,217 ("Miyazaki II"). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 59 of Miyazaki II meets all of the limitations of claims 45-47 of the instant application. For the rejection of claim 46 the fourth type of slits in claim 59 of Miyazaki can be construed as the second type of slits in claim 46 of the instant application. For the rejection of claim 47 the fourth type of slits in claim 59 of Miyazaki can be construed as the third type of slits in claim 47 of the instant application. For the rejection of claim 58 note that the last two lines of underlying claim 45 in Miyazaki meets the additional limitations of claim 58. The second type of slits in claim 45 of Miyazaki can be construed as the claimed fourth type of slits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1795

20. Claim 48 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 57 and 59 of Miyazaki II. Claim 47, from which claim 48 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 57 meets the additional limitations of claim 48.

This is a provisional obviousness-type double patenting rejection.

21. Claim 49 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 47 and 59 of Miyazaki II. Claim 47, from which claim 49 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 47 of Miyazaki II meets the additional limitations of claim 49.

This is a provisional obviousness-type double patenting rejection.

22. Claim 50 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 48 and 59 of Miyazaki II. Claim 45, from which claim 50 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 48 of Miyazaki II meets the additional limitations of claim 50.

This is a provisional obviousness-type double patenting rejection.

23. Claim 51 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 49 and 59 of Miyazaki II. Claim 45, from which claim 51 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 49 of Miyazaki II meets the additional limitations of claim 51.

This is a provisional obviousness-type double patenting rejection.

24. Claim 52 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 50 and 59 of Miyazaki II. Claim 47, from which claim 52 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 50 of Miyazaki II meets the additional limitations of claim 52.

This is a provisional obviousness-type double patenting rejection.

25. Claim 53 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 51, 47, and 59 of Miyazaki II. Claim 49, from which claim 53 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 51 of Miyazaki II meets the additional limitations of claim 53.

This is a provisional obviousness-type double patenting rejection.

26. Claim 54 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 52, 47, and 59 of Miyazaki II. Claim 53, from which claim 54 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 52 of Miyazaki II meets the additional limitations of claim 54.

This is a provisional obviousness-type double patenting rejection.

27. Claim 55 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 53 and 59 of Miyazaki II. Claim 45, from which claim 55 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 53 of Miyazaki II meets the additional limitations of claim 55.

This is a provisional obviousness-type double patenting rejection.

Art Unit: 1795

28. Claim 56 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 54 and 59 of Miyazaki II. Claim 55, from which claim 56 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 54 of Miyazaki II meets the additional limitations of claim 56.

This is a provisional obviousness-type double patenting rejection.

29. Claim 57 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 55 and 59 of Miyazaki II. Claim 45, from which claim 56 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 55 of Miyazaki II meets the additional limitations of claim 57.

This is a provisional obviousness-type double patenting rejection.

Art Unit: 1795

30. Claim 59 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 46 and 59 of Miyazaki II. Claim 48, from which claim 59 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 46 of Miyazaki II meets the additional limitation of claim 59.

This is a provisional obviousness-type double patenting rejection.

31. Claim 60 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 60 and 59 of Miyazaki II. Claim 45, from which claim 60 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 60 of Miyazaki II meets the additional limitation of claim 60.

This is a provisional obviousness-type double patenting rejection.

32. Claim 61 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 61 and 59 of Miyazaki II. Claim 60, from which claim 61 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 61 of Miyazaki II meets the additional limitation of claim 61.

This is a provisional obviousness-type double patenting rejection.

33. Claim 62 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 62 and 59 of Miyazaki II. Claim 45, from which claim 62 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 62 of Miyazaki II meets the additional limitation of claim 62.

This is a provisional obviousness-type double patenting rejection.

34. Claim 63 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 63 and 59 of Miyazaki II. Claim 45, from which claim 63 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 63 of Miyazaki II meets the additional limitation of claim 63.

This is a provisional obviousness-type double patenting rejection.

35. Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 64 and 59 of Miyazaki II. Claim 45, from which claim 64 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 64 of Miyazaki II meets the additional limitation of claim 64.

This is a provisional obviousness-type double patenting rejection.

36. Claim 65 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the combination of claims 65 and 59 of Miyazaki II. Claim 45, from which claim 65 depends, has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 65 of Miyazaki II meets the additional limitation of claim 65.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

37. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1795

38. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

39. Claims 45-48, 51, 55-60, and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 ("Winarta") in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka").

Addressing claims 45 and 46, Winarta discloses a biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61).

WInarta does not mention whether the biosensor has information of correction data generated for each production lot of the biosensor, which corresponds to characteristics concerning output of an electrical change resulting from a reaction between the sample liquid and the reagent layer and can be discriminated by a measuring device employing the biosensor.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers

Art Unit: 1795

and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a second type of slits. See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the electrode part as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08.

Addressing claim 47, Winarta discloses a biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

- a first insulating support (20) and a second insulating support (50);

- an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

- a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

- a reagent layer employed for quantifying the substrate included in the sample

Art Unit: 1795

liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support

(Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61).

WInarta does not mention whether the biosensor has information of correction data generated for each production lot of the biosensor, which corresponds to characteristics concerning output of an electrical change resulting from a reaction between the sample liquid and the reagent layer and can be discriminated by a measuring device employing the biosensor.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the

Art Unit: 1795

electrode part, which would be a third type of slits (note that claim 47 does not list a second type of slits, so the third type of slits could actually be a second type of slits. In any event, Kawanaka does also disclose a second type of slits – slits 28 (each segment can be construed as a separate slit) which form the static noise prevention means (col. 07:63 – col. 08:01)). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a type of slits for dividing the electrical conductive layer to define an area of the electrode part as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08.

Addressing claim 48, for the additional limitations of this claim see Figure 2 in Winarta and Figures 8, 9, 20, 22, 24, and 28-32 in Kawanaka.

Addressing claim 51, for the additional limitations of this claim see Figure 2 and col. 07:58-61 in Winarta.

Addressing claim 55, for the additional limitations of this claim see Figure 2 in Winarta and note spacer 40.

Addressing claim 56, for the additional limitation of this claim see Figures 1 and 2; col. 11:09-11; and col. 11:39-41 .

Addressing claim 57, for the additional limitation of this claim note element 52 in Figure 2.

Addressing claim 58, as for the reagent layer being formed by dripping a reagent, this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably “dripped”, from Applicant’s reagent, and

As for a fourth type of slits, these can be taken to be the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2, as they are not for forming electrodes, but means to “avoid potential static problems which could give rise to a noisy signal” – col. 07:63 to col. 08:01. They are also provided around a position where the reagent is dripped (Figure 2).

Addressing claim 59, Winarta only discloses linear slits. See Figure 2 in Winarta. However, to make the second type of slits arc-shaped is just a mere arbitrary change in shape, unless Applicant shows that the slit shape is significant. See MPEP 2144.04.IV.B.

Addressing claim 60, Winarta does not disclose providing a third type of slits and a fourth type of slits formed by processing the electrical conductive layer by a laser.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a third type of slits and a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a third type of slits for dividing the electrical conductive layer to define an area of the electrode part and a fourth type of slits as taught by Kawanaka in the invention of Winarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed can be conveyed to the measuring apparatus. For example, the third slits can indicate the particular analyte the test strip is configured to measure and the fourth slits can indicate calibration date. See col. 02:45 – col. 05:07 and col. 05:44 – col. 06:08.

As for the slits being formed using a laser, this is a product-by-process limitation that does not further patentably limit the slits. In any event Winarta discloses forming slits in the electrically conductive material using a laser. See col. 04:15-30 and col. 07:54-63.

Addressing claims 62-65, for the additional limitations of these claims see col. 07:44-51; col. 08:26-52; and col. 09:14-40.

40. Claims 49, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 ("Winarta") in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka") as applied to claims 45-48, 51, 55-60, and 62-65 above, and further in view of Ikeda et al. US 5,582,697 ("Ikeda").

Winarta does not disclose the electrode part further comprising a detecting electrode; however, Winarta does disclose providing a third electrode, W2, that could also function as a detecting electrode. As shown by Ikeda a third electrode located at the end of a capillary channel in a biosensor test strip could be used as a detecting electrode in addition to alternatively being involved in the actual sample measurement (abstract and Figure 1).

For claim 53 note that Winarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. Since electrode

Art Unit: 1795

W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) the sum of the area for electrode "R" (the counter/reference electrode) and the area of W2 (detecting /pseudo working electrode) will necessarily be greater than that of the W1 (the working electrode).

For claim 54 note that WInarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. Since electrode W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) it may have the same area as the counter electrode ("R").

41. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over WInarta in view of Kawanaka as applied to claims 45-48, 51, 55-60, and 62-65 above, and further in view of Fujiwara et al. US 6,004,441 ("Fujiwara").

WInarta as modified by Kawanaka does not appear to mention the possible widths of the slits; however, as noted in the rejection of claim 60 WInarata does disclose using a laser to form the slits.

Fujiwara discloses making slits in a metal film to make electrodes or a test strip type biosensor. The slits are made using a laser and be 70 microns (=0.07mm) in width. See the abstract and col. 02:52-59. In light of Fujiwara Applicant's claimed slit

Art Unit: 1795

width range of 0.005 mm to 0.3 mm is just a matter of scaling the biosensor to the expected volume range of sample, by , for example, making smaller more closely spaced electrodes for smaller expected sample volumes.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
October 11, 2008